Surgical Insights, Inc.

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SEP 1 2 2000

510(k) Summary K001642

Submitter: Surgical Insights, Inc.

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Phone number: (847) 866-1816

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Contact person: Jon T. Lea, Ph.D.

Date prepared: May 23, 2000

Trade name: InSight™ Image Guided Surgical System

Substantial equivalence claimed to:
1. StealthStation® System with FluoroNav™ module - 510(k) Number - K990214
2. VectorVision^2 (BrainLAB Navigation System) - 510(k) Number - K983831

Description:
The InSight™ System provides the surgeon with real-time visual feedback of the placement of instruments and implants within a patient's body. The system consists of a mobile cart that houses a computer, monitor, and optical localizer cameras, an imaging attachment for a conventional C-arm fluoroscope, and custom surgical instruments. Both the imaging attachment and the surgical instruments are outfitted with LEDs that are tracked by the optical localizers.

During surgery, images of the patient's anatomy are obtained with the C-arm while the position of the C-arm is simultaneously read. The images are displayed on the mobile cart monitor. The surgical instruments are used to guide an implant (e.g., drill guide and a Steinmann pin, respectively). The direction and location of placement are continually displayed onscreen with animated computer graphic representations; e.g, the path a Steinmann pin will take is indicated by a trajectory line coincident with the drill guide bore.

Intended use:
The InSight™ System is intended for use by a surgeon for intraoperative visualization of instrument trajectories and implant placement in either open or percutaneous procedures.

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Summary of technological characteristics:

The InSight™ System melds two novel technologies – a digital x-ray imager and optical localizer systems – along with a computer that controls their functions. The digital x-ray imager is the primary component of the C-arm imaging attachment, and provides linear, high resolution images of a patient's anatomy. The optical localizer cameras track LEDs mounted to a rigid object such as a surgical instrument. With an appropriate number of LEDs, the 3D position of the object can be continually monitored within a workspace volume 1 meter in diameter located approximately 1.5 meters from the optical localizer cameras.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2000

Jon T. Lea, Ph.D.
Vice President, Engineering
Surgical Insights, Inc.
1840 Oak Avenue
Evanston, Illinois 60201

Re: K001642
Trade Name: InSight™ System
Regulatory Class: II
Product Code: HAW
Dated: July 17, 2000
Received: July 19, 2000

Dear Dr. Lea:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001642

Device Name: InSight™ System

Indications for Use:

The InSight™ System is intended f r use by a surgeon for intraoperative visualization of instrument trajectories and implant placement in either open or percutaneous procedures. The InSight™ System is indicated for any medical condition where reference to a rigid anatomical structure, such as the skull, vertebra, or long bone, can be identified relative to a fluoroscopic image of the anatomy, and it is desired to direct instruments and/or implants into the anatomy. Additionally, the InSight™ System is indicated for use where an instrument or implant can be identified relative to another instrument or implant, and it is desired to direct the first instrument/implant into some alignment with the second instrument/implant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vodnes.

(Division Sign-
Division of Ge[illegible] Devices

510(k) Number K001642

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)